510(k) Summary of Safety and Effectiveness

K013442
page 1 of 1

(1) **Submitter's name:** Encore Orthopedics, Inc.
Submitter's address: 9800 Metric Blvd, Austin, TX 78758
Submitter's telephone number: (512) 834-6255
Contact person: Joanna Droege
Date summary prepared: October 16, 2001

(2) **Trade or proprietary device name:** PASS Spinal System
Common or usual name: Pedicle screw spinal system
Spinal interlaminal fixation orthosis
Classification name: Class II

JAN 1 5 2002

(3) **Legally marketed predicate device:** PASS Spinal System (K001024)

(4) **Subject device description:**

The subjects of this submission are the addition of polyaxial crosslink components for the PASS Spinal System (K001024). All components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

The hooks can be used for single or multiple level fixation. The polyaxial hooks have the same attachment mechanism of the PASS Spinal System polyaxial components cleared in K001024 and K012175.

The laminar hooks are inserted inferior and superior around the lamina and the polyaxial pedicle hooks are inserted inferior and superior around the pedicles. The double laminar hooks are available in standard and polyaxial configurations. The low profile of the hooks allows it to be used in conjunction with a pedicle screw assembly without any problem of superimposition.

The laminar hooks are inserted under the lamina and the polyaxial pedicle hooks are inserted under the pedicle. The low profile of the hook allows it to be used in conjunction with a pedicle screw assembly without any problem of superimposition.

(5) **Subject device intended use:**

The PASS Spinal System consists of pedicle screws, rods, nuts and crosslink members utilized to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system, the PASS Spinal System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

When used as a posterior, non-cervical, non-pedicle screw fixation syste, the PASS Spinal System is intended for hook fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), deformities (scoliosis, kyphosis and lordosis), tumor, pseudoarthrosis, trauma (fracture or dislocation) and/or previous failed fusion surgery.

(6) **Performance data:**

The Food and Drug Administration have established no performance standards applicable to pedicle screw spinal systems. However, static and fatigue compression testing of the PASS Spinal System was performed according to ASTM F1717-96.

(7) **Basis for substantial equivalence:**

The PASS Spinal System Hooks are equivalent to the other spinal systems commercially available that incorporate pedicle screws, rods, and crosslinking members.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2002

Ms. Joanna Droege
Regulatory/QA Manager
Encore Orthopedics
9800 Metric Boulevard
Austin, Texas 78758

Re: K013442
Trade Name: PASS Spinal System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spondylolisthesis Spinal Fixation Device System, Spinal Interlaminal Fixation Orthosis,
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: October 16, 2001
Received: October 17, 2001

Dear Ms. Droege:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____ K013442

Device Name: Additional Components to PASS Spinal System

Indications For Use:

Additional Components to PASS Spinal System

Indications For Use

The PASS Spinal System consists of pedicle screws, rods, nuts and crosslink members utilized to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013442

SK-19